5-23-2017

In Re: Amarin Corporation PLC

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 16-2640

IN RE: AMARIN CORPORATION PLC SECURITIES LITIGATION

James L. Reiss, Lead Plaintiff on behalf of all plaintiffs,
Appellants

On Appeal from the United States District Court
for the District of New Jersey
(D.N.J. No.: 3-13-cv-06663)
District Judge: Honorable Freda L. Wolfson

Argued on April 25, 2017

Before: SMITH, Chief Judge, MCKEE and RENDELL, Circuit Judges

(Opinion filed: May 23, 2017)

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OPINION[*]

RENDELL, Circuit Judge:

Appellant-Plaintiff James Reiss (the "Plaintiff") appeals an Order of the District Court dismissing his putative securities fraud class action complaint (the "Second Consolidated and Amended Class Action Complaint" or "SAC") against the Appellee-Defendant Amarin Plc., a biopharmaceutical corporation, and certain of its individual officers (the "Defendants"). The District Court held that the Plaintiff failed to state a claim because none of the eighty-seven statements made by the Defendants and

[*] This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

recounted in the SAC were false or misleading. For the reasons that follow, we agree with the District Court's reasoning and will affirm.

I. BACKGROUND

A. Factual Background

Amarin's primary drug is Vascepa, an ultra-pure omega-3 fatty acid product designed to reduce triglycerides in the blood stream. Triglycerides ("TGs") are a common form of fat molecule. During the Class Period (November 29, 2010 through October 16, 2013), the Defendants sought FDA approval of Vascepa for treatment of patients with elevated TGs who are already taking a statin drug like Lipitor (the "ANCHOR Indication"). The Defendants theorized that administering Vascepa in this regime would result in a statistically significant reduction of major adverse cardiac events like heart attacks. They have vigorously pursued ANCHOR because the potential treatment population is thirty-six million people.[1]

To support its application for the ANCHOR Indication, Amarin proposed conducting a 12-week trial (the "ANCHOR Study") to demonstrate the efficacy of the drug. Given its short duration, the ANCHOR Study could not measure cardiovascular outcomes directly as the clinical endpoint of the study. Such a measurement would require an expensive and time-consuming long-term outcomes study. Rather, Amarin

[1] Amarin secured FDA approval of Vascepa for another indication, the MARINE indication, to treat persons with "very high" TGs at risk of pancreatitis. But this population contained approximately four million potential patients.

proposed to rely on the reduction of TGs as a "surrogate endpoint," on the assumption that a significant reduction of TGs would lead to reduced major adverse cardiac events.

On July 14, 2008, senior Amarin officials met with the FDA to determine whether the design of its ANCHOR Study was "adequate to provide the clinical efficacy data necessary to support the proposed [ANCHOR] indication[.]" SAC ¶ 114. The FDA responded, as documented in the official minutes of that meeting (the "2008 Minutes") that it was "not aware" of any long-term outcomes trials demonstrating that the reduction of TGs in patients on statin therapy significantly reduces the risk of major adverse cardiac events. SAC ¶115. It then noted that three then-ongoing outcome studies, titled AIM-HIGH, ACCORD, and IMPROVE-IT, "while not designed to address this specific gap in knowledge, [would] provide important information on the incremental benefit of adding a second lipid-active drug to statin therapy." JA.483; SAC ¶¶ 4; 116. Consequently, the FDA stated that "before [it] would entertain granting [Vascepa] an indication . . . ," Amarin would "at a minimum" have to submit data from the ANCHOR Study and "initiate an appropriately-designed cardiovascular outcomes study" that was "well under way" by the time the FDA began its review. JA.484; SAC ¶21. The Defendants did not share the 2008 Minutes with investors.

Amarin later entered a Special Protocol Assessment ("SPA") Agreement with the FDA memorializing some of this feedback in July 2009 (the "2009 SPA"). An SPA Agreement binds the FDA as to design, methodological, and approval criteria for a given drug application, although the FDA may rescind an SPA if it identifies "a substantial scientific issue essential to determining the safety or effectiveness of [a] drug . . . after

the testing has begun." 21 U.S.C § 355(b)(5)(C)(ii). In the 2009 SPA, the FDA agreed with the proposed "design" of the ANCHOR Study, including Amarin's proposed "endpoints." JA.508. But when asked whether statistically significant results from the ANCHOR Study would "provide an adequate basis for approval" of the indication, the FDA responded only that "[t]his is a review issue." SAC ¶ 127. The Defendants did not share all of the FDA's comments in connection with the 2009 SPA with investors.

In April 2011, Amarin announced that the results of the ANCHOR Study showed statistically significant reduction of TGs in the ANCHOR population. However, around this time, two of the three outcomes studies mentioned by the FDA in 2008 (ACCORD and AIM-HIGH) failed to achieve their endpoints.[2] On a conference call between Amarin and the FDA on April 14, 2011, the FDA told Amarin that an advisory committee "was likely before the indication could possibly be granted."[3] SAC ¶ 247.

Four months later, the FDA and Amarin entered into a second SPA agreement (the "2011 SPA") covering the design and endpoints of the long-term outcomes study mentioned as a "minimum" requirement in 2008 (the "REDUCE-IT Study"). The FDA agreed with Amarin's design of the REDUCE-IT Study, but again declined to commit to approval criteria. *See* SAC ¶ 278 (noting that "approvability of the indication will be a review issue").

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[2] IMPROVE-IT, although not completed until after the Class Period, demonstrated "modest favorable results." *In re Amarin Corp. PLC Sec. Litig.*, No. CV-13-6663 (FLW) (TJB), 2016 WL 1644623, at *2 n.6 (D.N.J. Apr. 26, 2016); SAC ¶¶165–66.

[3] In reviewing a drug application the FDA may—or may not—convene an advisory committee ("AdCom") of experts for guidance. The FDA is not bound by this guidance.

By February 2013, the REDUCE-IT Study was substantially underway, so Amarin submitted a supplemental New Drug Application for ANCHOR. On October 16, 2013, however, the FDA convened an advisory committee and voted to reject the ANCHOR application because it found that there was insufficient data to support the use of reducing TGs as a surrogate endpoint. The FDA, shortly thereafter, rescinded the 2009 SPA citing the results from ACCORD, AIM-HIGH, and a third study not mentioned in the 2008 Minutes, HPS2-THRIVE, as establishing a substantial scientific issue.

The Defendants appealed the FDA's decision to rescind the 2009 SPA, but the appeal was denied. Reviewers, such as Drs. Rosebraugh and Jenkins, rejected Amarin's arguments and made clear that the 2008 Minutes "indicate[d] the fragile nature of the evidence supporting TG's hold onto surrogate status," SAC ¶134, and "that there were still concerns regarding [TG lowering]," SAC ¶137. Dr. Ketchum, one of the individual defendants, acknowledged understanding as much from these minutes in post-Class Period correspondence. The appeal decisions emphasized, however, that at the time of the 2008 Minutes and 2009 SPA, the FDA believed the scientific data supported TG lowering and thus that the FDA was justified in entering the 2009 SPA. The decision to rescind, Dr. Jenkins added, "was based on the accumulation and totality of scientific data and information, including reevaluation and improved understanding of the relevant scientific knowledge, that have become available since the ANCHOR trial began . . . ." JA.685.

B. Alleged Material Misrepresentations

Lead Plaintiff James Reiss then brought this securities fraud action, claiming violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934. He alleges that the Defendants intentionally misled investors as to the material risk that the FDA would require Amarin to complete an outcomes study at great cost and delay before granting the ANCHOR Indication, by omitting to disclose the FDA's "reservations" as stated in the 2008 Minutes and 2009 SPA. SAC ¶ 204. The Plaintiff then identifies eighty-seven statements drawn from press releases, offering announcements, prospectuses, and earnings call transcripts during the Class Period (the "Statements") that he alleges were false and misleading in light of these omissions.

The Plaintiff organizes the Statements into eight categories, but focuses on the first in this appeal. In that category, he identifies fourteen statements wherein the Defendants represented that a long-term outcome trial (REDUCE-IT) was "not required" to be completed or that the Defendants "[did] not believe" one "[would] be required" to be completed before the FDA approved the ANCHOR Indication.[4] SAC ¶¶ 235; 353. The Plaintiff alleges that these statements are false and misleading because the FDA had indicated approval would be a "review issue," and that an outcomes trial, "given the

[4] The other seven categories included: (1) statements purportedly representing that TGs were an accepted surrogate endpoint; (2) a statement characterizing the SPA agreement as "strong endorsement" of Amarin's strategy; (3) statements allegedly mispresenting the import of the AIM-HIGH and ACCORD studies; (4) statements misrepresenting the import of a Japanese TG study; (5) statements concerning the placebo in the ANCHOR Study; (6) statements purportedly mischaracterizing the level of enrollment required in the REDUCE-IT study; and (7) statements allegedly misrepresenting market demand of the drug.

failure of the ACCORD and AIM-HIGH trials, [was] *almost certainly* going to be required by the FDA prior to approval of ANCHOR." SAC ¶209(i) (emphasis added). The Plaintiff also alleges that various statements to the effect that Amarin was optimistic that the FDA would approve ANCHOR based on the ANCHOR Study amplified the misleading nature of the Statements.

C. The District Court Opinion

The District Court, in two comprehensive and thoughtful opinions, separately analyzed each category of statement and held that the Plaintiff failed to allege any false or misleading statements. *See In re Amarin Corp. PLC Sec. Litig.*, No. CV-13-6663 (FLW) (TJB), 2016 WL 1644623, at *1 (D.N.J. Apr. 26, 2016); *In re Amarin Corp. PLC*, No. 13-CV-6663 (FLW) (TJB), 2015 WL 3954190, at *1 (D.N.J. June 29, 2015).

It reasoned, *inter alia*, that had the FDA wished to condition approval of ANCHOR on completion of an outcomes trial, it would have explicitly said so. When viewed in context, the "use of the language 'review issue' impl[ied] that it [was] possible, although not guaranteed, that [the ANCHOR Study] would be an adequate basis for approval." *In re Amarin*, 2016 WL 1644623, at *10. Therefore, the Defendants' statements that completion of an outcomes trial was not required before approval were not misleading because "[t]hese statements merely accurately reflected the agreed terms of the 2008 Meeting and the 2009 SPA." *Id.* Similarly, any statements allegedly implying that TG lowering was an accepted surrogate endpoint were not misleading because "[u]nder the facts alleged, it is clear that at the time the 2009 SPA and the 2011 SPA were executed, the reduction of TGs was still an accepted surrogate for the reduction of

[major adverse cardiac events]." *Id.* at *17. For similar reasons, the District Court concluded that none of the other Statements were misleading as to the FDA's feedback in 2008 or 2009.

The Plaintiff appeals and argues that the District Court erred by "applying a heightened pleading standard," "weighing competing evidence," and "not considering the [S]tatements in the aggregate." Reiss Br. 20. He maintains that a reasonable investor would have been misled by the totality of the Defendants' Statements into believing that there was a "clear path to approval" for the ANCHOR Indication, when, in fact, there was not.[5]

After independently reviewing the record, we perceive no reason to disturb the District Court's reasoning and rulings.

II. DISCUSSION[6]

Section 10(b) of the Securities Exchange Act of 1934 prohibits fraud in connection with the purchase or sale of securities. *See* 15 U.S.C. § 78j(b). Rule 10b-5, in particular,

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[5] Oral Argument at 14:20–17:10, *In re: Amarin Corp. PLC Sec. Litig*, No. 16–2640, available at http:// www2.ca3.uscourts.gov/oralargument/audio/16-2640InReAmarinCorpPLC.mp3.

[6] The District Court had jurisdiction under 28 U.S.C. §1331. We have jurisdiction under 28 U.S.C § 1291. We exercise plenary review over the District Court's Order to grant a Rule 12(b)(6) motion to dismiss. *See In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277 (3d Cir. 2010). In so doing, we apply the Private Security Litigation Reform Act's heightened pleading standards, which require a private securities fraud complaint to "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u–4(b)(1).

At this stage we may rely on, in addition to the complaint itself, documents incorporated by reference and undisputed in authenticity, including publically-filed SEC disclosures. *See Winer Family Tr. v. Queen*, 503 F.3d 319, 327 (3d Cir. 2007).

makes it unlawful to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014) (quoting 17 C.F.R. § 240.10b–5(b)). To state a claim for securities fraud, a plaintiff must show (1) a material misrepresentation or omission, (2) scienter, (3) a nexus between the misrepresentation or omission and the purchase or sale of a security, (4) reliance, (5) economic loss, and (6) loss causation. *See In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277 (3d Cir. 2010).

The District Court dismissed the SAC under the first element, concluding that the Defendants' Statements contained no material misrepresentations or omissions because they were not materially misleading. A statement or omission is materially misleading if "there is 'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information available'" to that investor. *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988)).

We keep in mind, however, that Rule 10b-5 "do[es] not create an affirmative duty to disclose any and all material information." *Id.* at 44; *accord Oran v. Stafford*, 226 F.3d 275, 285 (3d Cir. 2000) ("Silence, absent a duty to disclose, is not misleading under Rule 10b–5." (quoting *Basic Inc.*, 485 U.S. at 239 n.17)). Rather, disclosure of material information is required "only when necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives*,

563 U.S. at 44 (alteration in original) (quoting 17 C.F.R. § 240.10b–5(b)).[7] As the Supreme Court has recently emphasized, "[e]ven with respect to information that a reasonable investor might consider material, companies can control what they have to disclose under these provisions by controlling what they say to the market." *Id*. at 45.

Here, we agree with the District Court that none of the Statements, in context, were misleading as to the FDA's feedback; consequently, we hold that the Defendants were not obligated to disclose the 2008 Minutes or 2009 SPA.

The lynchpin of the Plaintiff's omission theory of liability is his allegation that as the AIM-HIGH and ACCORD studies failed, it became increasingly likely, if not certain, that the FDA would reject TG lowering as a validated surrogate endpoint. Given this, he contends, the FDA was "certain" to require an outcomes trial to be completed prior to approval, rendering the Defendants' representations misleading.

But, in so arguing, we think the Plaintiff mischaracterizes the FDA's position on TG lowering during the Class Period. Viewed in their entirety, the SAC and documents incorporated by reference reveal that TG lowering, despite the open nature of the scientific question, remained a viable surrogate endpoint until 2013. In view of this, the Statements, even taken together with the Defendants' optimism, are not actionable.

[7] We therefore reject the Plaintiff's argument that the District Court applied an improper burden or weighed competing evidence. Rather, the District Court properly considered whether, in context, any of the Statements were false or misleading and appropriately relied on documents incorporated by reference into the SAC. Its analytical approach was sound.

We begin with the 2008 Minutes. At oral argument, the Plaintiff's counsel urged us to read the FDA's statement that it was "not aware" of any long-term studies to reflect its position that there was "no association" between TG lowering and reduction of cardiovascular risk.[8] But the FDA never stated that there was "no association." The FDA never stated that TG Lowering was not a valid surrogate endpoint either. To the contrary, the FDA expressly provided "minimum" requirements for consideration of Amarin's application based on this theory of proving efficacy. JA.484. Moreover, in the FDA's decision letter rejecting Amarin's appeal (from which the Plaintiff quotes extensively in support of his characterizations), Dr. Jenkins confirmed that "at the time of the [2008 Meeting], (as well as at the time of the ANCHOR SPA agreement) [the FDA] was still willing to accept TG lowering as a validated surrogate for reducing CV risk . . . ." JA.682. Thus, the 2008 Minutes actually show that TG lowering was an accepted surrogate endpoint in 2008.

Nonetheless, the Plaintiff urges us to focus on the failure of the ACCORD and AIM-HIGH studies. He insists the Defendants' application was doomed as a result of their failure because the FDA commented in 2008 that these studies would provide "important information." SAC ¶ 116. But the full text of that quote reads that ACCORD and AIM-HIGH, while important, were "not designed to address this specific gap in knowledge." JA.483. The FDA, thus, did not opine that AIM-HIGH and ACCORD would decide the issue conclusively. The post-Class Period documents show that in

[8] Oral Argument at 4:21.

reaching its decision to rescind, the FDA was swayed not only by ACCORD and AIM-HIGH, but also by a third study not mentioned in the 2008 Minutes, HP2S-THRIVE. *See* JA.947 (noting in a December 16, 2013 meeting that three studies, ACCORD, AIM-HIGH, and HP2S-THRIVE, "reduced the [FDA's] level of confidence"). We cannot say then, as the Plaintiff insists, that the FDA viewed the outcome of the AIM-HIGH or ACCORD as definitively deciding the TG question in 2008 or in 2011 after those studies failed.

The Plaintiff next points to the 2009 SPA, particularly that approval was a "review issue." SAC ¶ 127. But we do not see how this advances his argument. In the 2009 SPA, the FDA actually "agreed" with the design of the ANCHOR Study, meaning that it agreed with its selected surrogate endpoint. JA.508. As the District Court aptly noted, the FDA's use of the phrase "review issue" meant only that "it [was] possible, although not guaranteed" that a twelve-week efficacy would suffice. *In re Amarin*, 2016 WL 1644623, at *10. The FDA's entering into the 2011 SPA for REDUCE-IT *after* the ACCORD and AIM-HIGH studies failed further confirms that the FDA had yet to decide the issue, but was still willing to consider the application on this theory.

We think it clear from the 2008 Minutes, 2009 SPA, and 2011 SPA that the FDA never explicitly or even implicitly indicated that a long-term outcome trial would be required to be completed for approval. The FDA only wished to see that a long-term study was "well under way," JA.484, or "approximately 50% percent enroll[ed]," JA.406. While quantification of that requirement, in terms of enrollment figures, appears to have

been a matter of negotiation throughout the Class Period, there is no dispute, based on these documents, that *completion* of such a trial was not required for approval.

Finally, we note that documents incorporated by reference make it abundantly clear that the FDA did not *conclusively* reformulate its thinking on the state of the scientific literature supporting the TG lowering hypothesis until after it considered the "new" scientific evidence in 2013. JA.686; *see also* JA.685 (noting that the FDA's decision to rescind "was based on the accumulation and totality of scientific data and information, including *revaluation* and *improved understanding* of the relevant scientific knowledge, that have become available *since the ANCHOR trial began*" (emphasis added)); JA.686 (noting that the FDA "could not know the outcome of the ongoing [outcome studies]" and characterizing the "cumulative results" of those studies as "new scientific information" (underline in original)); JA.687–88 (concluding that "weight of evidence *no longer supports*" the use of TG lowering as a surrogate endpoint because of the "important new scientific evidence" (emphasis added)).

In sum, far from being "extremely likely (if not certain)" to reject TG lowering as a validated surrogate endpoint and require a completed outcomes study before granting the ANCHOR Indication, Reiss Br. 22, the FDA remained open to Amarin's strategy of demonstrating efficacy; no well-pled allegation supports the claim that the FDA reformulated its thinking prior to the advisory committee meeting.[9] We therefore decline

[9] At oral argument, the Plaintiff emphasized his allegation regarding the April 2011 teleconference wherein the FDA stated that an AdCom was likely. But we fail to see how this indicated that the FDA was correspondingly "likely" to require an outcomes study. It meant at most that the FDA would seek guidance on the TG issue.

to accept as true the allegation that the FDA was "certain" to require an outcomes study at the time of the Defendants' Statements, even in light of ACCORD's and AIM-HIGH's failure to produce supportive results.

Accordingly, we agree with the District Court that none of the Statements were false or misleading given the FDA's position on TG lowering. The Defendants never expressly stated or implied that the 2009 SPA guaranteed approval,[10] or that the FDA had conclusively accepted TG lowering as a validated surrogate during the Class Period.[11] As the District Court correctly noted, the Defendants are merely alleged to have stated, accurately, the minimum requirements for consideration as laid out in the 2008 Minutes.

We also find the Plaintiff's argument that a reasonable investor would have interpreted the Defendants' Statements as presenting a "clear path to approval" to be unpersuasive given Amarin's contemporaneous disclosures. The Defendants' publically-filed Form 10-Ks repeatedly warned investors that the FDA may rescind an SPA if it identifies a "substantial scientific issue." *See* JA.496, 521, 529, 536. The Defendants' 2011 Form 10-K, in particular, acknowledges that: "no outcomes study has been conducted evaluating [Vascepa for the ANCHOR Indication];" "Outcomes studies of

[10] The Defendants warned investors that SPAs, in fact, did *not* guarantee approval. *See* JA.536 ("Our SPAs with the FDA are not guarantees of FDA approval of Vascepa for the proposed ANCHOR and REDUCE-IT indications.").

[11] On this point, we disagree with Plaintiff's characterization of his second category of statements. He claims the Defendants represented, in his words, that "TG lowering was an accepted surrogate endpoint for a long-term CVD outcomes benefit." Reiss Br. 35. The text of the statements actually says that TGs were a "risk factor" for cardiovascular disease. SAC ¶ 194. The statements say nothing about the FDA's position on surrogacy and are therefore not actionable because the Plaintiff does not allege that TGs were not considered a risk factor at the time of the statements.

certain other lipid modifying therapies have failed to achieve the endpoints of such studies;" "[t]here can be no assurance as to the final indication approved by the FDA," JA.196–97; and "the agency could assert that additional studies or data are required to support a regulatory submission," JA.529.

As other courts have recognized, a reasonable investor understands that a "[c]ontinuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process." *Tongue v. Sanofi*, 816 F.3d 199, 211 (2d Cir. 2016) (alteration in original) (internal quotation marks omitted) (quoting *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015)). Here, a reasonable investor would not have been misled by the Defendants' Statements unless the FDA had foreclosed (or provided conditions that obtained during the class period under which it would foreclose) reliance on TG lowering as a surrogate endpoint. Because neither the 2008 Minutes nor the 2009 SPA, fairly characterized, bear out the Plaintiff's characterizations of the FDA's position, we agree that the Defendants did not have a duty to disclose them under the securities laws.

The Plaintiff also emphasizes to us the Defendants' optimistic projections of approval. But just because the Defendants were aware of the TG issue and optimistic that it would be decided in their favor does not necessarily mean their omissions are actionable. *See OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481, 496–97 (3d Cir. 2016) (holding that statement to that there was "no pending or . . . threatened . . . labor strike" was not misleading when all the plaintiff pled with particularity was a risk of a labor dispute and that the defendant "was aware of and was preparing for that risk"

(first alteration in original)); *City of Edinburgh Council*, 754 F.3d at 170 (noting that opinions are not actionable unless they are (1) not honestly believed and (2) lack a reasonable basis); *accord In re Merck & Co., Inc. Sec., Derivative & "ERISA" Litig.*, 543 F.3d 150, 166 (3d Cir. 2008).[12] The Plaintiff fails to allege that the Defendants did not honestly believe their projections (or their assessments of the scientific literature underlying those projections); nor are there allegations that the Defendants lacked a reasonable basis for so believing. To the contrary, the 2008 Minutes, taken in context, show that they did have a reasonable basis for believing the FDA would approve the ANCHOR Indication. The Plaintiff's reliance on the fact the FDA ultimately rejected TG lowering after a review of "new" scientific data would amount to pleading "fraud by hindsight, something our Court has long rejected." *OFI*, 834 F.3d at 497 (internal quotation marks omitted).

Finally, we disagree that *Zak v. Chelsea Therapeutics Int'l, Ltd*., 780 F.3d 597 (4th Cir. 2015), "compel[s]" reversal. Reiss Br. 26. In *Zak*, the FDA explicitly told the Defendants in an SPA that it "expected two successful efficacy studies before it would grant regulatory approval of the new drug" and later "warned . . . that a single successful study typically was not sufficient to support approval of a new drug." *Zak*, 708 F.3d at 602. Here, the FDA never required an outcomes study be completed prior to submission,

[12] Although the Plaintiff cites *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 135 S. Ct. 1318, 1329 (2015), a §11 case, as supporting its argument, we decline to decide whether *Omnicare* is applicable to §10(b) claims because even under the principles set forth in the Supreme Court's opinion in that case, our decision here would remain unchanged.

or even, like in *Zak*, indicated that one would typically be required in this situation. Rather, the FDA declined to adopt criteria for approval one way or the other, and waited to see how the scientific literature developed. *See* SAC ¶126 (noting ultimate approval is "a review issue"). *Zak*, therefore, does not help the Plaintiff.

We have considered the remainder of the Plaintiff's arguments as to why the Statements were false and misleading, but find them unavailing.

III. Conclusion

For the foregoing reasons, we will affirm the Order of the District Court.